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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,003	01/09/2001	Vijay R. Baichwal	T95-006-2	8531

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RICHARD ARON OSMAN  
SCIENCE AND TECHNOLOGY LAW GROUP  
75 DENISE DRIVE  
HILLSBOROUGH, CA 94010

EXAMINER

ANDRES, JANET L

ART UNIT PAPER NUMBER

1646

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/758,003

Applicant(s)

BAICHWAL ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6,10-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6,10-27 and 29-34 is/are rejected.
- 7) ☒ Claim(s) 28 and 35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 27 August 2003 is acknowledged. Claims 1, 3, 5, 6, and 10-35 are pending and under examination in this application. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### ***Claim Rejections/Objections Withdrawn***

2. The objection to the specification and to the title is withdrawn in response to Applicant's amendment.

3. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as indefinite is withdrawn in response to Applicant's cancellation of this claim.

### ***Claim Rejections Maintained/New Grounds of Rejection***

4. The rejection of claims 1, 3, 5, 6, 10-27, and 29-34 under 35 U.S.C. 112, first paragraph, as lacking written description is maintained for reasons of record in the office action of 3 June 2003.

Applicant has amended the claims to require that the encoded peptide be immunologically distinguishable from the serine analogue (claim 1 and depending claims) or that the nucleic acid not hybridize with the nucleic acid that encodes the serine analogue (claim 3 and depending claims). Applicant argues that the claims require a specific function. Applicant further argues that the claims require specific structure in that they require at least ten amino acids be encoded.

Applicant's arguments have been fully considered but have not been found to be persuasive. Neither a requirement that the polynucleotide encode at least 10 amino acids, nor the negative requirements for hybridization or antigenicity are sufficient to describe the claimed

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genera of nucleic acids. The claims are drawn to sequences encoding regions of at least 10 or 11 amino acids around the threonine mutation at position 514; the different dependent claims specify different sequences containing this mutation. Thus, as stated previously, the claims encompass polynucleotides that vary widely in length and composition; the only common feature among the claims is that the polynucleotides encode the single residue at position 514. No particular structural or functional characteristics are ascribed to regions of 10 amino acids around this region. They do not define a genus of polynucleotides having common characteristics.

There is no way to tell which variants would be members of such a genus. The inclusion of the limitation that the encoded polypeptide be antigenically distinct from the serine analogue, or that the polynucleotide not hybridize with the polynucleotide encoding the serine analogue, does not serve to define a genus. There are no common characteristics required by such limitations: no features are required that would define or be characteristic of the genus as a whole. All that is required by such limitations is that the molecule differ somehow from the serine-containing version, not that they be linked themselves in any way. Further, antigenicity or lack thereof or the ability to hybridize are not defining characteristics; they are not linked to any common biochemical functions or required structures that would identify members of a genus.

5. The rejection of claims 1, 3, 5, 6, 10-27, and 29-34 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate with the scope of the claims is maintained for reasons of record in the office action of 3 June 2003.

Applicant has amended the claims as set forth above and argues that the specification discloses a novel variant and the pending claims are all restricted to probes or reagents for making them which distinguish the novel variant.

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Applicant's arguments have been fully considered but have not been found to be persuasive. The claims are not restricted to probes; they use the open language "comprising"; thus they encompass all molecules that contain the required sequence. As stated in the office action of 3 June 2003 and discussed above, the claims thus encompass polynucleotides of very different sequences. The specification does not provide guidance for the use of the wide variety of polynucleotides encompassed by the claims. As stated above, the negative limitations with respect to antigenicity or hybridization are not definitive; they require no common features and thus one of skill could not make polynucleotides with the same features. They further do not provide a function; one of skill would not know how to use a protein merely because it was antigenically distinct from another. Thus it would require undue experimentation for the skilled artisan to make and use polynucleotides commensurate in scope with the claims.

***Claim Rejections - 35 USC § 101***

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 5 and 6 are newly rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Because the claims do not require that the host cell be isolated, they potentially encompass cloned or transgenic humans, which are not patentable.

***Allowable Subject Matter***

Claims 28 and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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CLAIMS 1, 3, 5, 6, 10-27, AND 29-34 ARE REJECTED. CLAIMS 28 AND 35 ARE OBJECTED TO.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov](mailto:yvonne.eyler@uspto.gov).

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.  
November 4, 2003

  
**JANET ANDRES**  
**PATENT EXAMINER**